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IS 3987 (2006): Sorbitol solution (70 percent) for cosmetic industry [PCD 19: Cosmetics]



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भारतीय मानक
सोरबिटोल सॅल्युशन (70 प्रतिशत) सौंदर्य प्रसाधन
उद्योग के लिए — विशिष्टि
(तीसरा पुनरीक्षण)

Indian Standard
SORBITOL SOLUTION (70 PERCENT) FOR
COSMETIC INDUSTRY — SPECIFICATION
(*Third Revision*)

ICS 71.100.70

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BUREAU OF INDIAN STANDARDS
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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

The original standard was first revised in 1977 and second revision was carried out in 1983. Initially while reviewing this standard the Committee had agreed to indicate separately the essential and optional requirements. Subsequently this was found non-implementable for certification and therefore in the second revision, only a single set of requirements was stipulated. In this revision the Committee has decided to incorporate non-crystallizing grade sorbitol solution with lower total hexahydric alcohol content which is required by the industry, for Dentifrice preparations along with crystallizing grade.

Sorbitol solution is an aqueous solution consisting essentially of *D*-sorbitol and a small amount of mannitol and other isomeric polyhydric alcohols. It is usually prepared by the hydrogenation of natural sugars.

Sorbitol is an ingredient valued in cosmetic preparations for its humectants and emollient properties.

This standard contains clauses 3.2 and 4.1 which call for agreement between the purchaser and the supplier.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

SORBITOL SOLUTION (70 PERCENT) FOR COSMETIC INDUSTRY — SPECIFICATION

(Third Revision)

1 SCOPE

This standard prescribes the requirements and methods of sampling and test for sorbitol solution (70 percent).

2 REFERENCES

The following standards are necessary adjuncts to this standard:

<i>IS No.</i>	<i>Title</i>
265 : 1993	Specification for hydrochloric acid (<i>fourth revision</i>)
266 : 1993	Specification for sulphuric acid (<i>third revision</i>)
1070 : 1992	Reagent grade water (<i>third revision</i>)
2088 : 1983	Methods for determination of arsenic (<i>second revision</i>)
4905 : 1968	Methods for random sampling
14648 : 2005	Methods of test for microbiological examinations of cosmetics and cosmetic raw material (<i>first revision</i>)

3 REQUIREMENTS

3.1 Description

The material shall be a clear, colourless to faintly yellow, odourless, syrupy liquid having a pleasant sweet taste.

3.2 Colour

The colour of the material shall be as agreed to between the purchaser and the supplier.

3.3 Types/Classification

Sorbitol is classified into two types, namely:

- a) crystallizing grade, and
- b) non-crystallizing grade.

3.4 The material shall also comply with the requirements given in Table 1 when tested according

to the methods prescribed in Annexes. Reference to the relevant Annexes is given in col 5 of Table 1.

4 PACKING AND MARKING

4.1 Packing

The size and material of construction of the containers shall be subject to agreement between the purchaser and the supplier.

4.2 Marking

The containers shall be securely closed and marked with the following information:

- a) Name and type of the material;
- b) Manufacturer's name and/or recognized trade-mark, if any;
- c) Net mass of the material; and
- d) Batch number, in code or otherwise, to enable the lot of manufacturer to be traced back from records.

4.3 BIS Certification Marking

The containers may also be marked with the Standard Mark.

4.3.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

5 SAMPLING

The method for preparing representative test samples of the material and the criteria for conformity shall be as prescribed in Annex M.

6 QUALITY OF REAGENTS

Unless specified otherwise, pure chemicals and distilled water (*see* IS 1070) shall be used in tests.

Table 1 Requirements for Sorbitol Solution
(Clause 3.4)

Sl No.	Characteristic	Type I Crystallizing Grade	Type II Non-crystallizing Grade	Method of Test, Ref to	
				Annex	IS No.
(1)	(2)	(3)	(4)	(5)	(6)
i)	pH	5 to 7.5	5 to 7.5	A	—
ii)	Total solids, percent by mass	68 to 72	68 to 72	B	—
iii)	Relative density, 25°C	1.28 to 1.31	1.28 to 1.31	C	—
iv)	Refractive index, 25°C	1.455 to 1.465	1.455 to 1.465	D	—
v)	Total hexahydric alcohols, <i>Min</i>	65	50	E	—
vi)	Reducing sugar, percent by mass, <i>Max</i>	To pass the test	To pass the test	F	—
vii)	Arsenic (as As ₂ O ₃), parts per million, <i>Max</i>	2	2	G	—
viii)	Heavy metals (as Pb), parts per million, <i>Max</i>	10	10	H	—
ix)	Sulphated ash, parts per million, <i>Max</i>	0.1	0.1	J	—
x)	Chloride (as Cl), percent by mass, <i>Max</i>	0.005	0.005	K	—
xi)	Sulphates (as SO ₄), percent by mass, <i>Max</i>	0.01	0.01	L	—
xii)	Microbial count: Total viable count, cfu/g, <i>Max</i>	1 000	1 000	—	14648

ANNEX A

[Table 1, Sl No. (i)]

DETERMINATION OF pH

A-1 APPARATUS

pH meter.

A-2 PROCEDURE

Take 100 ml of the sorbitol solution (70 percent) and determine pH of the solution by means of pH meter.

ANNEX B

[Table 1, Sl No. (ii)]

DETERMINATION OF TOTAL SOLIDS**B-1 PRINCIPLE**

Water is removed by keeping the material under vacuum at 80°C and the residue is weighed.

B-2 PROCEDURE

Weigh accurately about 1 g of the material in a suitable tared weighing bottle. Keep at a temperature of 80°C at pressure not more than 5 mm Hg for 6 h. Transfer it into a desiccator, cool and weigh.

B-3 CALCULATION

$$\text{Total solids, percent by mass} = 100 \times \frac{M_1}{M_2}$$

where

M_1 = mass of the residue in the weighing bottle, in g;
and

M_2 = mass of the material taken for the test, in g.

ANNEX C

[Table 1, Sl No. (iii)]

DETERMINATION OF RELATIVE DENSITY**C-1 APPARATUS**

C-1.1 Relative Density Bottle, with well-fitting ground-glass joint of capacity 50 ml.

C-1.2 Water-Bath, maintained at $25.0 \pm 0.2^\circ\text{C}$.

C-2 PROCEDURE

C-2.1 Clean and dry the relative density bottle, weigh and fill with recently boiled and cooled water at about 25°C . Fill to overflowing by holding the bottle on its side in such a manner as to prevent entrapment of air bubbles. Insert the stopper and immerse in the water-bath at $25.0 \pm 0.2^\circ\text{C}$. Keep the entire bulb completely immersed in water and hold at that temperature for 30 min. Carefully remove any water which has exuded from the capillary opening. Remove from the bath,

wipe completely dry, cool to room temperature and weigh.

C-2.2 Clean and dry the bottle again and processed in C-2.1 using the material previously brought to a temperature of about 25°C in place of water.

C-3 CALCULATION

$$\text{Relative density at } 25^\circ\text{C}/25^\circ\text{C} = \frac{A - B}{C - B}$$

where

A = mass of the relative density bottle with the material, in g;

B = mass of the relative density bottle, in g; and

C = mass of the relative density bottle with water, in g.

ANNEX D

[Table 1, Sl No. (iv)]

DETERMINATION OF REFRACTIVE INDEX**D-1 APPARATUS**

D-1.1 Abbe Refractometer — The temperature of the refractometer shall be controlled to within $\pm 0.1^\circ\text{C}$ and, for this purpose, it shall be provided with a thermostatically controlled water-bath and a motor-driven pump to circulate water through the instrument. The instrument shall be standardized, following the manufacturer's instructions, with a liquid of known

purity and refractive index or with a glass prism of known refractive index. Distilled water, which has a refractive index of 1.333 0 at 20°C , is satisfactory liquid for standardization.

D-1.2 Light Source — If the refractometer is equipped with a compensator, a tungsten lamp or a daylight bulb may be used. Otherwise monochromatic light, such as an electric sodium vapour lamp shall be used.

D-2 PROCEDURE

Filter the material through a filter paper to remove any impurities. Adjust the temperature of the refractometer to $25.0 \pm 0.1^\circ\text{C}$. Ensure that the prisms are clean and dry; then place a few drops of the sample

on the lower prism. Close the prisms, tighten firmly with the screw head and allow to stand for one or two minutes. Adjust the instrument and light to obtain the most distinct reading possible and determine the refractive index.

ANNEX E

[Table 1, *Sl No. (v)*]

**DETERMINATION OF TOTAL HEXAHYDRIC
ALCOHOLS (AS SORBITOL)**

E-1 PRINCIPLE

The method is based upon the reaction of sorbitol and other related polyhydric alcohols with sodium metaperiodate (NaIO_4) in acidic aqueous solution to produce formaldehyde and formic acid. This is a quantitative reaction and also specific for compounds containing hydroxyl groups on adjacent carbon atoms. The reaction mixture is then treated with sodium arsenite solution to remove excess of periodic acid. Finally excess of sodium arsenite is titrated against standard iodine solution in presence of sodium bicarbonate and potassium iodide. The quantity of iodine solution corresponding to the hexahydric alcohol content is determined after carrying out a blank test under identical conditions.

E-2 REAGENTS

E-2.1 Sodium Metaperiodic Solution [2.14 Percent (*m/v*)] — Dissolve 2.14 g of sodium metaperiodate in 100 ml of water. Store the solution in an amber coloured bottle in the dark.

NOTE — Sodium metaperiodate shall be a white crystalline powder containing not less than 98 percent sodium metaperiodate. If metaperiodate does not dissolve, it is not of reagent quality and a new supply should be obtained.

E-2.2 Dilute Sulphuric Acid, 1 : 10 (*v/v*).

E-2.3 Sodium Bicarbonate

E-2.4 Potassium Iodide Solution, 20 percent (*m/v*).

E-2.5 Standard Sodium Arsenite Solution (0.2 N) — Dissolve 4.946 g of arsenic trioxide in a mixture of 20 ml of sodium hydroxide solution (20 percent *m/v*) and 20 ml of water. Dilute to 400 ml with water and add dilute hydrochloric acid (about 2 N) until the

solution is neutral. Dissolve 2 g of sodium bicarbonate in the solution and dilute to 500 ml with water.

E-2.6 Standard Iodine Solution (0.1 N)

NOTE — The iodine solution should be always standardized against sodium thiosulphate before use.

E-3 PROCEDURE

Using a weighing bottle, transfer into a measuring flask a well-mixed and accurately weighed sample (0.50 to 0.55 g). Dissolve it and make up the solution to 100 ml with water. Transfer 10 ml of this solution to a conical flask. Add 20 ml of sodium metaperiodate solution and 2 ml of dilute sulphuric acid, replace the glass stopper and heat the reaction mixture on a boiling water bath for 15 min. Cool to room temperature, add 2 g of sodium bicarbonate and 25 ml of sodium arsenite solution. Mix well and add 5 ml of potassium iodide solution. Allow the reaction mixture to stand for 15 min. Titrate the excess of sodium arsenite against standard iodine solution until the first yellow colour just appears. Carry out a blank determination simultaneously under similar test conditions.

E-4 CALCULATION

$$\text{Total hexahydric alcohols (as sorbitol), percent by mass} = \frac{18.22 (V - V_1)}{M} \times N$$

where

V = volume of standard iodine solution required for the material, in ml;

V_1 = volume of standard iodine solution required in the blank determination, in ml;

N = normality of standard iodine solution, and

M = mass in g of the material taken for the test, in g.

ANNEX F

[Table 1, *Sl No. (vi)*]

TEST FOR REDUCING SUGARS

F-1 REAGENTS

F-1.1 Copper Reagent — Dissolve with aid of heat 150 g of sodium citrate, 130 g of anhydrous sodium carbonate and 10 g of sodium bicarbonate in about 650 ml of water. Cool, add a solution containing 16 g of copper sulphate in 150 ml of water, dilute to 1 000 ml with water and filter.

F-1.2 Glacial Acetic Acid Solution, 2.4 percent (v/v).

F-1.3 Iodine Solution, Standard, 0.05 N.

F-1.4 Standard Sodium Thiosulphate Solution, 0.05 N.

F-1.5 Hydrochloric Acid Solution, 6 percent (v/v).

F-1.6 Starch Solution — Titrate 0.5 g of starch with

5 ml of water and add this, with constant stirring to sufficient water to produce about 100 ml. Boil for a few minutes, cool and filter.

F-2 PROCEDURE

Weigh accurately 3.5 g and add 20 ml of copper reagent and heat in such a manner that the solution boils in 4 min, and continue boiling for further 3 min. Cool rapidly and add 100 ml of 2.4 percent (v/v) solution of acetic acid followed by 20.0 ml of 0.05 N iodine. Add with continuous swirling 25 ml of 6 percent (v/v) solution of hydrochloric acid and when any precipitate has redissolved titrate the excess of iodine with 0.05 N sodium thiosulphate solutions, using starch solution, added towards the end of the titration as indicator.

Not less than 12.8 ml of 0.05 N sodium thiosulphate is required.

ANNEX G

[Table 1, *Sl No. (vii)*]

DETERMINATION OF ARSENIC

G-1 PRINCIPLE

Arsenic present in a solution of the material is reduced to arsine, which is made to react with mercuric bromide paper. The stain produced is compared with a standard stain.

G-2 REAGENTS

G-2.1 Mixed Acid — Dilute one volume of concentrated sulphuric acid with four volumes of water. Add 10 g of sodium chloride for each 100 ml of the solution.

G-2.2 Ferric Ammonium Sulphate Solution — Dissolve 64 g of ferric ammonium sulphate in water

containing 10 ml of mixed acid and make up to one litre.

G-2.3 Concentrated Hydrochloric Acid—See IS 265.

G-2.4 Stannous Chloride Solution — Dissolve 80 g of stannous chloride ($\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) in 100 ml of water containing 5 ml of concentrated hydrochloric acid.

G-3 PROCEDURE

Carry out the test as prescribed in IS 2088, adding into the Gutzeit bottle, 2 ml of ferric ammonium sulphate solution, 0.5 ml of stannous chloride solution and 25 ml of sample solution.

For comparison, use 1g material and 0.002 mg of arsenic trioxide stain.

ANNEX H

[Table 1, Sl No. (viii)]

DETERMINATION OF HEAVY METALS

H-1 PRINCIPLE

Brown colour produced by the material with sodium sulphide solution is matched with that obtained with standard lead solution.

H-2 APPARATUS

H-2.1 Nessler Cylinders, 50 ml capacity.

H-3 REAGENTS

H-3.1 Standard Lead Solution — Dissolve 1.600 g of lead nitrate in 100 ml of water to which 1 ml of nitric acid has been added. Make the volume to 1 litre. Dilute 1 ml of this solution again to 1 litre. One millilitre of this solution is equivalent to 0.01 mg of lead (as Pb).

H-3.2 Hydrogen Sulphide Solution, saturated solution, freshly prepared.

H-3.3 Dilute Acetic Acid

H-4 PROCEDURE

Mix 2.000 g of the material and 2 ml of dilute acetic acid with water to make 25 ml. Transfer to a Nessler cylinder. In another Nessler cylinder, pipette out 2 ml of dilute acetic acid and 2 ml of standard lead solution and make the volume to 25 ml with water. Add 10 ml of hydrogen sulphide solution to each Nessler cylinder, mix, allow to stand for 10 min and compare the colours in both the cylinders.

H-4.1 The material shall be taken to have passed the test, if the intensity of colour produced with the material is not greater than that in the control test.

ANNEX J

[Table 1, Sl No. (ix)]

DETERMINATION OF SULPHIDE ASH

J-1 REAGENT

J-1.1 Concentrated Sulphuric Acid, see IS 266.

J-2 PROCEDURE

Weigh accurately about 10 g of the material in a tared crucible. Ignite, gently at first, until the material is thoroughly charred, cool, moisten the residue with 1 ml of sulphuric acid and ignite gently till the carbon is completely consumed. Cool the crucible in a desiccators and weigh till constant mass is obtained.

NOTE — Carry out the ignition in a place protected from air currents and use as low a temperature as possible to effect the combustion of carbon.

J-3 CALCULATION

$$\text{Sulphated ash, percent by mass} = \frac{m}{M} \times 100$$

where

m = mass of the residue, in g; and

M = mass of the material taken for the test, in g.

ANNEX K

[Table 1, Sl No. (x)]

DETERMINATION OF CHLORIDES

K-1 PRINCIPLE

The turbidity produced with silver nitrate solution is matched with that obtained with standard chloride solution.

K-2 APPARATUS

K-2.1 Nessler Cylinders, 50 ml capacity.

K-3 REAGENTS

K-3.1 Silver Nitrate Solution, 2 percent.

K-3.2 Dilute Nitric Acid, 4 N.

K-3.3 Standard Hydrochloric Acid, exactly 0.02 N.

K-4 PROCEDURE

Weigh accurately 1.4 g of the material and transfer to a Nessler cylinder. Add 30 ml of water and mix; then add 1 ml each of dilute nitric acid and silver nitrate

solution. Dilute to the mark and shake well. Carry out a control test in another Nessler cylinder using 0.1 ml of standard hydrochloric acid and the same quantities of other reagents as used with the material. Allow to stand for 5 min protecting from direct sunlight and

compare the turbidity.

K-4.1 The material shall be taken to have not exceeded the limit prescribed in Table 1, if the turbidity with the material is not greater than that in the control test.

ANNEX L

[Table 1, Sl No. (xi)]

DETERMINATION OF SULPHATES

L-1 PRINCIPLE

The turbidity produced with barium chloride solution as matched with that obtained with standard sulphuric acid.

L-2 APPARATUS

L-2.1 Nessler Cylinder, 50 ml capacity.

L-3 REAGENTS

L-3.1 Dilute Hydrochloric Acid, 4 N.

L-3.2 Barium Chloride Solution, 10 percent.

L-3.3 Standard Sulphuric Acid, 0.02 N, accurately standardized.

L-4 PROCEDURE

Transfer 1.0 g of the material to a Nessler cylinder and add about 30 ml of water to it. Mix and add 1 ml of dilute hydrochloric acid and 3 ml of barium chloride solution. Dilute to the mark and shake well. Carry out a control test using 0.1 ml of standard sulphuric acid and the same quantities of the other reagents as used with the material. Allow both the Nessler cylinders to stand for 10 min and compare the turbidity.

L-4.1 The material shall be taken to have not exceeded the limit prescribed in Table 1, if the turbidity produced with the material is not greater than that in the control test.

ANNEX M

(Clause 5)

SAMPLING OF SORBITOL SOLUTION (70 PERCENT) FOR COSMETIC INDUSTRY

M-1 GENERAL REQUIREMENTS OF SAMPLING

M-1.0 In drawing, preparing, storing and handling and test samples, the following precautions and directions shall be observed.

- a) Samples shall not be taken in an exposed place.
- b) Sampling instrument shall be clean and dry.
- c) Precautions shall be taken to protect the samples, the material being sampled, the sampling shall be mixed as thoroughly as possible by suitable means.
- d) Samples shall be placed in clean, dry and air-tight glass or other suitable containers.
- e) Sample containers shall be of such size that they are almost completely filled by the sample.
- f) Each sample container shall be sealed air-tight with a suitable stopper after filling, and marked with full details of sampling, the date of sampling and the year of manufacture of the material.

M-2 SCALE OF SAMPLING

M-2.1 Lot

All the containers in a single consignment of the material drawn from a single batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of different batches of manufacture, the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

M-2.1.1 Samples shall be tested from each lot for ascertaining conformity of the material to the requirements of this standard.

M-2.2 The number of containers (n) to be chosen from the lot shall depend on the size of the lot (N) and shall be as given in Table 2.

M-2.3 The containers to be selected for sampling shall be chosen at random from the lot and for this purpose random number table (see IS 4905) shall be

used. In case such tables are not available, the following procedure may be adopted:

Starting from any containers, count them as 1, 2, 3.....*r* and so on in a systematic manner, where *r* is the integral part of (*N*/*n*). Every *r*th container thus counted shall be withdrawn from the lot, till the requisite sample is obtained.

M-3 TEST SAMPLES AND REFEREE SAMPLE

M-3.1 Preparation of Test Samples

M-3.1.1 Draw with an appropriate sampling instrument a small portion of the material from different parts of each container selected (see Table 2). The total quantity of the material drawn from each container shall be sufficient to conduct the tests for all the characteristics given under 3 and Table 1 and shall be not less than 250 g.

M-3.1.2 Thoroughly mix all portions of the material drawn from the same container. Out of these portions, equal quantities shall be taken from each selected containers and shall be well mixed together so as to form a composite sample weighing not less than 500 g. This composite sample shall be divided into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

M-3.1.3 The remaining portion of the material from each container (after the quantity needed for the formation of composite samples has been taken) shall be divided into three equal parts, each part weighing not less than 100 g. These parts shall be immediately, transferred to thoroughly dried bottles which are then sealed air-tight with stoppers and labeled with all the particulars of sampling given under M-1.7. The material in each sealed bottle shall constitute an individual test sample. These individual samples shall be separated into three identical sets of samples in such a way that each set has an individual test sample representing each container selected. One of these three sets shall be sent

to the purchaser, another to the supplier and the third kept for the referee.

M-3.2 Referee Sample

The referee sample shall consist of a composite sample (see M-3.1.2) and a set of individual samples (see M-3.1.3) marked for this purpose and shall bear the seals of the purchaser and the supplier. It shall be kept at a place agreed between the purchaser and the supplier and shall be used in case of dispute between the two.

M-4 NUMBER OF TESTS

M-4.1 Tests for total hexahydric alcohols content shall be conducted on each of the individual sample (see M-3.1.2).

M-4.2 Tests for the remaining characteristics shall be conducted on the composite sample (see M-3.1.2).

M-5 CRITERIA FOR CONFORMITY

M-5.1 For Individual Samples

The mean (\bar{x}) and the range (*R*) for the test results shall be calculated (range being the difference between the maximum and the minimum test result).

M-5.1.1 The lot shall be declared to have satisfied the requirement for sorbitol if the value of the expression ($\bar{x} - 0.6 R$) is equal to or greater than 65.

M-5.2 For Composite Sample

The test results on the composite sample shall meet the corresponding specified requirement.

M-5.3 A lot shall be declared as conforming to this specification, if it satisfied the requirements for each of the specified characteristics. If the requirements for any of the characteristics are not met, the lot shall be declared not to have satisfied the requirements of the specification.

Table 2 Number of Containers to be Selected for Sampling
(Clauses M-2.2 and M-3.1.1)

Sl No.	Lot Size	Number of Containers to be Selected
	(<i>N</i>)	(<i>n</i>)
(1)	(2)	(3)
i)	3 to 50	3
ii)	51 to 200	4
iii)	201 to 400	5
iv)	401 to 650	6
v)	651 and above	7

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